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Application Number 10627358 WY & TEL **TRANSMITTAL** Filing Date July 25, 2003 **FORM** First Named Inventor Peter Migaly Art Unit (to be used for all correspondence after initial filing) Examiner Name Attorney Docket Number 290194-00001 Total Number of Pages in This Submission **ENCLOSURES** (Check all that apply) After Allowance communication Fee Transmittal Form Drawing(s) to Group Appeal Communication to Board Licensing-related Papers Fee Attached of Appeals and Interferences Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) Petition Amendment/Reply Petition to Convert to a Proprietary Information After Final Provisional Application Power of Attorney, Revocation Status Letter Affidavits/declaration(s) Change of Correspondence Address Other Enclosure(s) (please Terminal Disclaimer Extension of Time Request Identify below): Request for Refund Return Postcard Express Abandonment Request CD, Number of CD(s) Information Disclosure Statement Remarks Certified Copy of Priority Document(s) Response to Missing Parts/ Incomplete Application Response to Missing Parts under 37 CFR 1.52 or 1.53 SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT Firm Individual name Debra. Anderson Signature Date 2004 February 11 CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.

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This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

PETER MIGALY : COMBINATION THERAPY FOR

DEPRESSION, PREVENTION OF

Filed: July 25, 2003 : SUICIDE, AND VARIOUS MEDICAL

AND PSYCHIATRIC CONDITIONS

Attorney Docket No.: 290194-00001

INFORMATION DISCLOSURE STATEMENT

February 11, 2004

Mail Stop PATENT APPLICATION Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313

Sir:

Pursuant to the provisions of 37 CFR Sections 1.56, 1.97 and 1.98, Applicant submits herewith copies of the foreign patent document references and non-patent literature document references cited on the attached Forms PTO/SB/08A and PTO/SB/08B for consideration during prosecution of this application.

This Statement is filed solely for the purpose of complying with the pertinent rules of the Office and is not intended to be a substitute for an independent evaluation by the Examiner of the art cited or an independent search by the Examiner, and no representation of any nature is made or intended by the filing of this Statement.

Respectfully submitted,

Debra Z. Anderson

Registration Number 44,506

Eckert Seamans Cherin & Mellott, LLC

600 Grant Street, 44th Floor

Pittsburgh, Pennsylvania 15219 Telephone: 412-566-1910

Attorney for Applicant

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			U.S. PATENT DOC	JMENTS	······································
Examiner Initials	Cite No.1	U.S. Patent Document Kind Code (if known)	Name of Patentee or Applicant	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	Α	5,780,051	Eswara et al.	07-14-1998	
	В	6,159,963	Beasley et al.	12-12-2000	
	C_	6,399,608	Dawson	06-04-2002	
	D	5,589,512	Norden	12-31-1996	
	П	2002003514	Tsai et al.	03-21-2002	
	F	6,147,072	Bymaster et al.	11-14-2000	
	G	6,395,727	Guadagno et al.	05-28-2002	
	Ι	5,500,343	Blum et al.	03-19-1996	
		5,591,884	DeNinno et al.	01-07-1997	
	J	4,310,524	Wiech et al.	01-12-1982	
	K	2002004004	Taylor	04-04-2002	
	Г	2002001632	Taylor	02-07-2002	
	М	6,322,503	Sparhawk, Jr.	11-27-2001	
	N	6,066,643	Perry	05-23-2000	
	0	6,174,882	Yelle	01-16-2001	
	Р	6,121,259	Yelle	09-19-2000	
	Q	6,352,984	Yelle	03-05-2002	
	R	6,348,455	Yelle	02-19-2002	
	S	5,958,921	Tollefson	09-28-1999	
	Т	6,582,737	Hirsh et al.	06-24-2003	

				FOR	EIGN PATENT DOCUMEN	rs		
Examiner Initials	Cite No.1	Office ³	Foreign Patent Do Number ⁴	cument Kind Code ⁵ (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T6
	J	wo	99/61027		Eli Lilly and Co	12-02-1999		
	V	EP	0958824A2		Eli Lilly and Co	11-24-1999		
	W	wo	95/00154		Hemisphere Limit	01-05-1995		1
	Х	wo	99/58130		Pharmacia & Upjo	11-18-1999		
	Υ	wo	01/51041		Laboratorios Ph	07-19-2001		
	Z	wo	01/51040		Laboratorios Ph	07-19-2001	-	_
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U.S. Falent and Tradellian Cince. U.S. F Complete if Known **Application Number** INFORMATION DISCLOSURE July 25, 2003 Filing Date STATEMENT BY APPLICANT First Named Inventor Peter Migaly Group Art Unit **Examiner Name** Attorney Docket Number 290194-00001

				U.S. PATENT DOCU	JMENTS	
Examiner Initials	Cite No.1	U.S. Patent Docum Number Kind (if kn	Code ²	Name of Patentee or Applicant	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	AA	2002005180		Faour et al.	05-02-2002	
	AB	2001004894		Faour et al.	12-06-2001	
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	FOREIGN PATENT DOCUMENTS									
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¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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INFO	DRMATION	4 D	ISCLOSURE	Filing Date	July 25, 2003
STATEMENT BY APPLICANT			APPLICANT	First Named Inventor	Peter Migaly
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	(use as many s	sheet	s as necessary)	Examiner Name	
Sheet	33	of	3	Attorney Docket Number	290194-00001

	,	OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	T
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume issue number(s), publisher, city and/or country where published.	T ²
	AC	MICHAEL E. THASE; M.D.; "What Role Do Atypical Antipsychotic Drugs Have in Treatment-Resistant Depression?"; The Journal of Clinical Psychiatry; February, 2002; Pages 95-103; 63:2; Physicians Postgraduate Press, Inc., Memphis, Tennessee	
	AD	JAMBUR ANANTH; "Treatment-Resistant Depression"; Psychother Psychosom; 1998; Pages 61-70; 67; S. Karger AG, Basel, Switzerland	
	AE	D. SOUERY ET AL.; "Treatment resistant depression: methodological overview and operational criteria"; European Neuropsychopharmacology; 1999; Pages 83-91; 9; Elsevier Science B.V./ECNP; Amsterdam, The Netherlands	
	AF	MARK W. VINER, M.D. ET AL.; "Low-dose Risperidone Augmentation of Antidepressants in Nonpsychotic Depressive Disorders with Suicidal Ideation"; Journal of Clinical Psychopharmacology; February, 2003; Pages 104-106; Vol. 23, No. 1; Lippincott Williams & Wilkins; Philadelphia, Pennsylvania	
	AG	DE ADSON, M.D. ET AL.; "An Open Trial of Quetiapine for Anxiety in Patents Receiving an SSRI"; Society of Biological Psychiatry Annual Meeting; May 16-18, 2002; Philadelphia, Pennsylvania	
	AH	SHIGEHIRO HIROSE, M.D. and CHARLES R. ASHBY, JR., PH.D.; "An Open Pilot Study Combining Risperidone and a Selective Serotonin Reuptake Inhibitor as Initial Antidepressant Therapy"; Journal of Clinical Psychiatry; August, 2002; Pages 733-736; 63:8; Physicians Postgraduate Press, Inc., Memphis, TN	
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Examiner Date Considered			
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